

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 2, 2021

Ian Kerr Lution Labs, LLC 11888 N. 138th Street Scottsdale, AZ 85259

Subject: Device Determination for Lution Labs, LLC

Product Name: Hylight[™] Surface Protect Platinum

EPA Pre-Application Number: 98771PA1 Application Date: November 11, 2020 Action Case Number: 00217141

Dear Mr. Kerr:

This letter is in response to your request, submitted on November 11, 2020, for an Agency determination on whether the product, "HylightTM Surface Protect Platinum" manufactured and marketed by Lution Labs, LLC, must be registered as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The following supporting information was submitted:

- 8570-1 Application for Device Determination;
- Receipt for PRIA M009 Online Payment (November 11, 2020) (Pay.gov Tracking ID: 26QECHT4; EPA Tracking ID: 76049442040);
- Label for the Hylight[™] Surface Protect Platinum Product Booklet, identifying the page numbers for the label and information addressing the data requirements; and
- Draft Confidential Statement of Formula (CSF) (November 20, 2020).

Description of Apparatus and Mode of Action

This product is a surface coating that provides bacteriostatic, mildewstatic, fungistatic, and algaestatic finish to the treated surface. The surface coating is a solution containing titanium dioxide (TiO²) and nanosilver that is applied by spray to hard and porous surfaces. According to the Hylight™ Surface Protect Platinum Product Booklet's product specifications, the product works in the day and night where the TiO² is activated in the presence of light to decompose microorganisms, known as photocatalytic oxidation, and the nanosilver works in the absence of light to "offer antibacterial and biofilm resistance."¹

 $^{^1}$ Hylight $^{\scriptscriptstyle\mathsf{TM}}$ Surface Protect Product Booklet at 4.

Pesticidal Claims

Hylight[™] Surface Protect Platinum Label:

"Hylight™ Platinum is a patented, easy to use device that works mechanically to bond to an applied surface to provide round-the-clock, long lasting surface coating offering an advanced combination of effective and durable antimicrobial surface protection on the market."

Ingredients statement indicates active ingredients are silver and titanium dioxide.

Hylight[™] Surface Protect Product Booklet (Labelling):

"Hylight™ Platinum is a supplemental residual antimicrobial surface coating that effectively inhibits the growth of bacteria, fungi, and mold that cause unpleasant odors, discoloration, staining, deterioration or corrosion on surfaces to which it is applied. The product can be used as a final bacteriostatic finish on treated surfaces."

"Effective against microbes."³

"Combined with nanosilver antibacterial agents and TiO² decomposition strength for long term health protection."

"Night-time: Nano silver- antibacterial, biofilm resistance."5

"Day-time: TiO^2 decomposes the bacteria through photocatalytic oxidation properties."

"The active ingredient in this product is effective against odor causing bacteria and fungi, bacteria and fungi which cause staining and discoloration, and algae as a static agent."

"This product can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algae static activity." 8

"It is recommended to reapply every year to ensure that the surface coating continuous protects and inhibits microbes, such as SARS CoV-2 and others."

² Hylight[™] Surface Protect Product Booklet at 4.

³ Hylight[™] Surface Protect Product Booklet at 4.

⁴ Hylight[™] Surface Protect Product Booklet at 4.

⁵ Hylight[™] Surface Protect Product Booklet at 4.

⁶ Hylight[™] Surface Protect Product Booklet at 4.

⁷ Hylight[™] Surface Protect Product Booklet at 10.

⁸ Hylight[™] Surface Protect Product Booklet at 10.

⁹ Hylight[™] Surface Protect Product Booklet at 10.

"Indoor/ Interior application – Low light antimicrobial activity." ¹⁰

Determination

EPA has reviewed your request and determined that the product, as the supporting material describes it, is a pesticide. FIFRA defines as pesticide, in relevant part, as "any substance or mixture... intended for preventing, destroying, repelling, or mitigating any pest." EPA believes that HylightTM PLATINUM is a pesticide because it contains substances—nanosilver and titanium dioxide (TiO₂)—to achieve a desired pesticidal effect. 12

EPA determines whether a product is intended for a pesticidal purpose by evaluating whether,

- (1) the seller or distributer "claims, states, or implies (by labeling or otherwise)" that the substance (1) "can or should be used as a pesticide," or (2) "consists of or contains an active ingredient and . . . can be used to manufacture a pesticide";¹³
- (2) the seller or distributer "has actual or constructive knowledge that the substance will be used, or is intended to be used, for pesticidal purpose"; ¹⁴ and
- (3) the substance "consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose . . . , [or] (2) use for manufacture of a pesticide."¹⁵

EPA finds that HylightTM PLATINUM is intended for pesticidal purpose. First, HylightTM PLATINUM contains two ingredients—nanosilver and TiO₂—that function as active ingredients and has no significant commercially valuable other than use for pesticidal purposes. ¹⁶ Specifically, the product specifications outlined in the product booklet indicates that the antibacterial coating works in the presence of light where titanium dioxide decomposes bacteria through photocatalytic oxidation, and the nanosilver provides antibacterial and biofilm resistance in the absence of light. ¹⁷ Photocatalytic oxidation is a chemical process, and the free radicals and reactive oxygen species achieve their pesticidal effects through chemical processes. Silver is a known pesticide that has been registered since 1954 for use as a disinfectant, sanitizer, and material preservative. Second, HylightTM PLATINUM's labeling makes several pesticide claims as referenced in the Pesticide Claim section in this letter indicating that the product can or should be used as a pesticide which include but not limited to the "coating effectively inhibits the growth of bacteria, fungi, and mold that cause unpleasant odors, discoloration, staining, deterioration or corrosion on surfaces to which

¹⁰ Hylight[™] Surface Protect Product Booklet at 12.

¹¹ FIFRA § 2(u), 7 U.S.C. § 136(u); see also 40 C.F.R. § 152.3.

¹² This is consistent with past EPA M009 Determinations where EPA determined that products containing titanium dioxide relying on photocatalysis and pesticidal effects through chemical processes were pesticides. *See, e.g.*, 96781PA1 decision from February 10, 2021

¹³ 40 C.F.R. § 152.15(a). "Active ingredient" is defined as a substance that "will prevent, destroy, repel, or mitigate any pest." 7 U.S.C. § 136(a)(1); 40 C.F.R. § 152.3.

¹⁴ 40 C.F.R. § 152.15(c).

¹⁵ 40 C.F.R. § 152.15(b).

¹⁶ See 40 C.F.R. § 152.15(b)(1).

¹⁷ Hylight[™] Surface Protect Product Booklet at 4.

it is applied, offering a final bacteriostatic, fungistatic, and algae static finish. ¹⁸ Third, Lution Labs who distributes or sells this product has made the pesticidal claims that "Nano silver offers antibacterial and biofilm resistance," ¹⁹ and "TiO² decomposes the bacteria through photocatalytic oxidation properties." ²⁰ Therefore, EPA considers this product to be a pesticide that is subject to registration under FIFRA Section 3.

Conclusion

Based on the information provided, EPA has determined that this product is a pesticide subject that should be registered with EPA before sale and distribution. For additional information and compliance assistance, see Appendix A. If you have any questions, please contact Stacey Grigsby by phone at 703-305-6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

Regulatory Management Branch II Antimicrobials Division (7510P)

Office of Pesticide Programs

Jacqueline Hardy

¹⁸ See 40 C.F.R. § 152.15(a)(1).

¹⁹ Hylight[™] Surface Protect Product Booklet at 4.

²⁰ 40 C.F.R. § 152.15(a)(1); Hylight[™] Surface Protect Product Booklet at 4.

Appendix A: Compliance Assistance

If you would like to distribute, sell, or offer to sell your product, it must be registered with the EPA pursuant to FIFRA Section 3.²¹ Note that distributing a pesticide that is not so registered is a violation of FIFRA Section 12(a)(1)(A) and may be subject to enforcement action.

Because your product is considered a pesticide subject to registration, EPA did not review your labels, websites, or other marketing materials for false or misleading claims. If you choose to register your pesticide, EPA will review your product label at that time.

State Information

Some states require registration of pesticides. Please check with the state where you plan to sell your pesticide to determine their requirements, including requirements for efficacy data.²²

Importing Pesticides or Devices

Importers of all FIFRA-regulated pesticides and devices must comply with FIFRA Section 17(c)(1) and U.S. Customs and Border Protection (CBP) regulations.²³ No imported pesticide or device may be adulterated, misbranded, or otherwise violative of FIFRA. Importing pesticides and devices is prohibited without a completed EPA Notice of Arrival of Pesticides and Devices (EPA NOA). The EPA NOA information may be submitted on paper using EPA Form 3540-1 or electronically via any CBP-authorized electronic data interchange system.²⁴

²¹ For more information on how to register a pesticide, see Environmental Protection Agency, Pesticide Registration Manual, https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

²² For more information. See EPA's website on State and Territorial Pesticide Agencies, https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/state-and-territorial-pesticide-agencies.
²³ 19 C.F.R. §§ 12.110-12.117.

²⁴ For more information, see EPA's website on importing and exporting pesticides and devices, https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices.